

**Opportunity Title:** FDA Fellowship in Development of Methods to Measure Neutralizing Anti-SARS-CoV-2 Antibodies

**Opportunity Reference Code:** FDA-CBER-2023-02

**Organization** U.S. Food and Drug Administration (FDA)

**Reference Code** FDA-CBER-2023-02

**How to Apply** *Connect with ORISE...on the GO!* Download the new ORISE GO mobile app in the [Apple App Store](#) or [Google Play Store](#) to help you stay engaged, connected, and informed during your ORISE experience and beyond!

A complete application consists of:

- An application
- Transcripts – [Click here for detailed information about acceptable transcripts](#)
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- One educational or professional recommendation

All documents must be in English or include an official English translation.

If you have questions, send an email to [ORISE.FDA.CBER@orau.org](mailto:ORISE.FDA.CBER@orau.org). Please include the reference code for this opportunity in your email.

**Application Deadline** 4/28/2023 3:00:00 PM Eastern Time Zone

**Description** *\*Applications will be reviewed on a rolling-basis, and this opportunity will remain open until filled.*

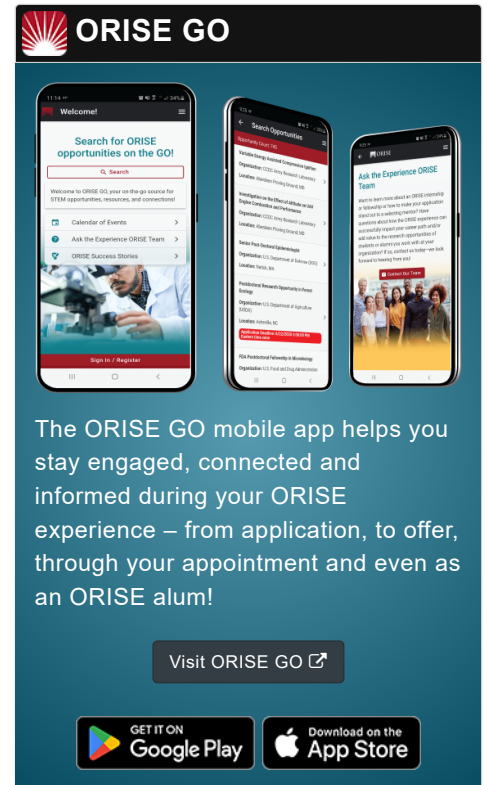
A research opportunity is available in the Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) in Silver Spring, Maryland.

The participant will join a research program that studies methods to detect neutralizing antibody activity in serum or plasma against viruses, and the effect of neutralizing antibodies in commercially produced Immune Globulin therapies in animal models. The current work of the laboratory is focused upon development of a BSL-2 method to reliably measure neutralizing antibody activity against SARS-CoV-2 in convalescent plasma, to provide a safe and fast method for selection of high-titer donations for COVID-19 therapy. The research team has already developed and tested a similar assay for H1N1 influenza antibodies.

The candidate will conduct research in close association with experimental biologists in developing and optimizing the SPR neutralization assay for convalescent human serum/plasma, and animal serum (from animals immunized against SARS-CoV-2).

Under the guidance of a mentor, the selected candidate will be involved in, but not limited to, the following activities:

- Theory and techniques of Surface Plasmon Resonance methods for binding/inhibition detection and characterization; mathematical methods for determining binding characteristics, and protein interaction kinetics;
- Methods for measuring antibody-mediated viral neutralization for SARS-CoV-2, such as pseudotype virus assays and SARS-CoV-2 virus-based assays (the ORISE Fellow will not be required to work directly with live SARS-CoV-2 virus);



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- Optimization of SPR-based methods, including experimental conditions, sample treatment, and reagent requirements;
- Methods to ascertain structural characteristics of SARS-CoV-2 binding to its receptors;
- Strategies for development of reference standards, how international standards are developed, and how to test candidate reference SARS-CoV-2 antibody reagents.

**Anticipated Appointment Start Date: First half of 2023; start date is flexible**

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The initial appointment is for three to four months, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

## Qualifications

The qualified candidate should have received a master's or doctoral degree in one of the relevant fields (e.g. Virology, Biology, Molecular Biology, Structural Biology, Immunology, Chemistry, Biophysics, Physics), or be currently pursuing one of the degrees with completion before prior to the start of the appointment. Degree must have been received within the past five years.

**Preferred Skills:**

- Experience in virology; cell-based aseptic techniques; purification and characterization of proteins in cell-based and mammalian systems; and molecular biology techniques
- Experience in basic lab work, such as sterile tissue culture techniques, protein

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purification, Western blotting, common molecular biology and virological techniques, and bioassay development

- Experience with advanced methods such as Surface Plasmon Resonance or similar binding detection and characterization methods

**Eligibility Requirements**

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Engineering** (2 👁)
  - **Life Health and Medical Sciences** (48 👁)

**Affirmation**

Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)

Will your degree be received prior to the start of your appointment?